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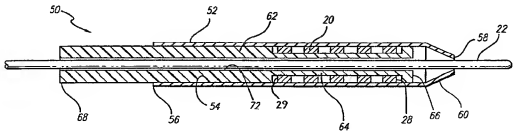
(54) Title: SELF-EXPANDING STENT DELIVERY SYSTEM AND METHOD OF USE



(57) Abstract: A stent delivery system (50, 74) having a stent pusher (62, 82) for delivering and implanting stents (20) is disclosed. The stent delivery system (50, 74) has a tubular catheter (52, 76) with a tapered distal end (58, 78), and the stent pusher (62, 82) is disposed coaxially therein so that the leading edge (66, 90) is adjacent to the tapered region. A recessed diameter region (64, 88) at the distal end of the stent pusher (62, 82), allows a self-expanding stent (20) to be mounted to the stent pusher (62, 82) and covered by the catheter (52, 76). As the stent pusher (62, 82) passes through the tapered region (58, 78), the leading edge (66, 90) bears the resisting load instead of the distal end (28) of the stent (20) during deployment. In another embodiment, an inner sleeve (94) is passed coaxially through an inner lumen (92) of the stent pusher (82) and extends from the distal end (84) of the stent pusher (82). It is attached to the distal end (80) of the catheter (76) linking movement of the catheter (76) and the inner sleeve (94). The stent (20) is deployed by pushing on the inner sleeve (94) while holding the stent pusher (82) immobile, which retracts the catheter (76) to expand the stent (20) beginning at the stent proximal end (29) and progressing to the stent distal end (28).

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SELF-EXPANDING STENT DELIVERY SYSTEM AND METHOD OF USE

BACKGROUND OF THE INVENTION

This invention relates to systems for the delivery of expandable devices, which are commonly referred to as "stents", within a body lumen such as an artery, and for the subsequent expansion of the stent therein to maintain the patency of the body lumen. The invention is particularly suitable for the delivery of the stents after an angioplasty procedures has been performed.

Percutaneous transluminal coronary angioplasty (PTCA) is now a widely practiced procedure for treating coronary artery disease. In a typical PTCA procedure, a dilatation catheter having an inflatable, relatively inelastic balloon on the distal end thereof is advanced through a patient's arterial system until the deflated balloon crosses an atherosclerotic lesion to be dilated. The balloon is inflated to a predetermined size with radiopaque liquid at relatively high pressures (e.g., up to 8.1 bars (8 atmospheres) or more) in order to compress the atherosclerotic plaque and to dilate the artery in the stenotic region. After the dilation process, the balloon is deflated so that the catheter can be removed from the body. Due to the enlarged arterial passageway, increased and improved blood flow results.

In typical PCTA procedures, a guiding catheter having a preformed distal end first is introduced percutaneously into the patient's arterial system and is advanced therein until the distal tip of the catheter is disposed in the ostium of a coronary artery. A guide wire is slidably disposed within an inner lumen of a dilatation catheter and both the guide wire and the catheter are advanced through the guiding catheter to the distal end of the guiding catheter. The guide wire is advanced first out of the guiding catheter through an opening in the distal tip of the dilatation catheter into the patient's coronary anatomy until the distal end of the guide wire crosses the lesion to be dilated. Before inserting the guide wire into the dilation

catheter, and based on the coronary anatomy, the cardiologist usually shapes the distal end of the guide wire to facilitate steering it through the patient's tortuous coronary arteries. Once the guide wire is in place, the dilatation catheter is advanced out of the distal tip of the guiding catheter over the guide wire until the deflated balloon on the distal end of the dilatation catheter is positioned across the lesion. The position of the balloon is monitored by the cardiologist through fluroscopy or some other radiographic method. The balloon is inflated to a suitable pressure to dilate the stenosis, the balloon then is deflated, and the dilation catheter, with or without the guide wire, then is removed from the patient's vasculature.

For a more detailed description of the angioplasty procedures and the devices used in such procedures, reference is made to U.S. Patent No. 4,332,254 to Lundquist; U.S. Patent No. 4,323,071 to Simpson and Robert; U.S. Patent No. 4,439,185 to Lundquist; U.S. Patent No. 4,468,224 to Enzmann et al.; U.S. Patent No. 4,516,972 to Samson; U.S. Patent No. 4,538,622 to Samson et al.; U.S. Patent No. 4,554,929 to Samson et al.; U.S. Patent No. 4,569,347 to Frisbie; U.S. Patent No. 4,571,240 to Samson et al.; U.S. Patent No. 4,616,652 to Simpson; U.S. Patent No. 4,748,982 to Horzewski et al.; U.S. Patent No. 5,300,085 to Yock; U.S. Patent No. 5,496,346 to Horzewski et al.; and U.S. Patent No. 5,626,600 to Horzewski et al.

On occasion, during an angioplasty procedure, the inflation of the balloon causes a dissection in the arterial lining, e.g., a dissection of the stenotic plaque or the arterial intima. When the balloon is deflated after such a dilation, blood can flow between the arterial wall and the dissected lining can become undesirably constricted. In addition, the dissected lining can form a "flap" which constricts and/or temporarily occludes the artery, thereby partially or completely blocking the blood flow.

Several post-angioplasty methods have been proposed to re-secure a dissected lining to the artery wall. For example, the dilatation catheter can be removed after the angioplasty procedure has been performed and replaced with a

perfusion catheter, i.e., a catheter which has an expandable member at the distal end which, when the expandable member is expanded, allows blood to perfuse through the expandable member. The balloon of the perfusion catheter presses the dissected tissue lining against the arterial wall for an extended period until, hopefully, the dissected lining is re-secured to the arterial wall. Blood perfuses through the expanded member so that ischemic conditions are minimized or eliminated distally of the expanded member. However, to accomplish a lining repair procedure with a perfusion catheter, the catheter typically must be left in the patient with the expandable member expanded for an extended period, e.g., fifteen minutes or more, before the lining can reattached to the artery. Examples of perfusion catheters are disclosed in U.S. Patent No. 4,790,315 to Mueller et al.; U.S. Patent No. 4,998,539 to Delsanti; U.S. Patent No. 5,034,001 to Garrison et al.; and U.S. Patent No. 5,002,560 to Machold et al.

Much development work also has been recently performed with respect to using expandable stents in situations where long-term expansion in an arterial or other bodily lumen is desired, such as in the instances described above. Expandable stents and the method of use of these expandable stents are described, for example, in U.S. Patent No. 5,603,721 to Lau et al.; U.S. Patent No. 5,421,955 to Lau et al.; U.S. Patent No. 5,514,154 to Lau et al.; U.S. Patent No. 4,655,771 to Wallsten; U.S. Patent No. 4,733,665 to Palmaz; U.S. Patent No. 4,739,762 to Palmaz; U.S. Patent No. 4,762,128 to Rosenbluth, Japanese Patent Application No. 57-89859, published Jun. 4, 1982, and European Patent Application Publication No. 0 183 372, published Jun. 9, 1986.

Other recent developments include stent delivery systems such as that disclosed in U.S. Patent No. 5,158,548 to Lau et al. This stent delivery system has an expandable stent in a contracted condition positioned on an expandable member, such as an inflatable balloon, which inflatable balloon is disposed on the distal portion of an elongated catheter body. A guide wire extends through an inner lumen within the elongated catheter body and out of the catheter body distal end. A

tubular protective sheath is secured by its distal end to the portion of the guide wire which extends out of the distal end of the catheter body and fits over the stent mounted on the expandable member on the distal end of the catheter body.

Another stent delivery system is disclosed in U.S. Patent No. 5,458,615 to Klemm et al. This delivery system includes an elongated delivery sheath and a catheter disposed within an outer lumen of the sheath having an expandable member on its distal extremity. An expandable stent is mounted on the expandable member of the catheter. The distal portion of the sheath tapers down and is tucked within an elastic cone during transport of the stent to a damaged region of the patient's body lumen. A manipulating device is provided on the proximal end of the delivery system to effect relative axial movement between the sheath and the catheter to expose the stent mounted on the expandable member to allow the expansion of the stent by the expansion of the expandable member.

Still another stent delivery system is disclosed in U.S. Patent No. 5,634,928 to Fischell et al. This integrated catheter system uses a balloon angioplasty catheter placed through a central passageway of a stent delivery catheter to enable balloon angioplasty and stent delivery to be accomplished with a single device.

Some stent delivery systems use stent pushers to deploy the stent. An example of a stent pusher is shown in U.S. Patent No. 4,580,568 to Gianturco. In this device, a stent is compressed to a reduced diameter which is several times smaller than its expanded diameter. The stent is positioned in a passageway in the vascular system by means of a sheath while the stent is retained in the compressed size. A flat-ended catheter/stent pusher is advanced through the sheath to hold the stent in place in the passageway while the sheath is withdrawn from the passageway, allowing the stent to expand in the passageway into its expanded shape to hold the passageway open. This technology is also discussed in the article "Tracheobronchial Tree: Expandable Metallic Stents Used In Experimental And Clinical Applications" by Gianturco et al., Radiology, vol. 158, pp. 309-12 (published December 5, 1986).

What has been needed and heretofore unavailable is a stent delivery system that is capable of negotiating tortuous vessels and of crossing tight stenoses while at the same time configured to easily deliver a stent.

SUMMARY OF THE INVENTION

The present invention is directed to a method and apparatus for a stent delivery system for delivering an unexpanded stent to a patient's body lumen, the stent delivery system comprising a tubular catheter having a tapered and pliable distal end, a proximal end, and an inner lumen extending therethrough; a rigid cylindrical-shaped stent pusher having a proximal end, and a leading edge at a distal end defining a first diameter, wherein the stent pusher is disposed at least partially within the catheter lumen; a recessed region of the stent pusher underlying the catheter having a second diameter smaller than the first diameter to receive the stent so that the outside diameter of the stent is at most equal, and in the preferred embodiment is equivalent, to the first diameter; an inner lumen extending coaxially through the stent pusher; and a guide wire extending through the inner lumen of the stent pusher.

In the present invention, the leading edge of the stent pusher bears the load encountered when the stent is deployed through the tapered distal end of the catheter. This is preferable to having the distal end of the stent bear the load directly, as is the case in various prior art systems.

In an alternative embodiment of the present invention, the stent delivery system is configured to allow a stent to expand along its length beginning at the proximal end and progressing towards the distal end until the stent is entirely expanded. To permit this manner of stent expansion, a stent delivery system according to the present invention further comprises a rigid inner sleeve which extends coaxially over the guide wire and through the lumen of the stent pusher, the

inner sleeve having a length that is longer than the length of the stent pusher and a distal end that is attached to the distal end of the catheter.

To deploy a stent using a stent delivery system according to the invention, the cardiologist positions the distal end of the stent delivery system at the lesion, maintains a hold on the stent pusher while pushing the inner sleeve in the distal direction. As the inner sleeve moves in the distal direction, the catheter that is attached to the inner sleeve is caused to move in the distal direction as well. The distal movement of the catheter slowly exposes first the proximal end of the unexpanded stent and then the distal end of the unexpanded stent.

In various other alternative embodiments of the present invention, the distal end of the catheter is tapered and may include a longitudinal slit, perforations, or overlapping surfaces which form a spiral. These features minimize the friction that is generated between the distal end of the catheter and the stent pusher, thus enabling the distal end of the stent pusher to pass through the distal end of the catheter with ease and little resistance.

The delivery system according to the present invention preferably is introduced percutaneously into the patient's arterial system using a conventional Seldinger technique which commonly employed in PTCA procedures. The guide wire is steerable so that the entire stent delivery assembly can be steered through the patient's arterial system until the stent is positioned at the desired arterial location.

Once the stent is at the desired location, which commonly is referred to as the "target site", the stent is deployed by translating the catheter to uncover the stent. If the stent is of the self-expanding type, the stent will expand to its final shape and size automatically at the target site. If the stent is not self-expanding, a balloon on the catheter is inflated in order to expand the stent beyond its elastic limit within the target site, pressing the stent against the arterial lining. The expandable member or balloon then is deflated to disengage the catheter from the expanded stent and to facilitate its removal of the stent delivery system from the patient. A stent delivery system according to the present invention allows for an expandable stent to be

rapidly and safely deployed within a patient's vascular system or other body lumen and further allows for the stent delivery system to be removed quickly after the stent has been expanded and delivered at the desired target site.

These and other advantages of the present invention will become apparent from the following detailed description and the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a cross-sectional view of a conventional stent delivery system using a stent pusher, an outer catheter, and a stent situated at the distal end of the catheter.

FIG. 2 is a cross-sectional view of another conventional stent delivery system wherein the distal end of the catheter is tapered.

FIGS. 3A, 3B, 3C, and 3D are a side, front, front, and side elevational views of a tapered cone located at the distal end of the catheter of the conventional stent delivery system of FIG. 2. FIGS. 3A and 3B depict a cone with at least one slit. FIG. 3C is a front elevational view of a tapered cone having overlapping surfaces which are formed into a spiral. FIG. 3D is a side elevational view of an alternative embodiment of a cone positioned at the distal end of the catheter which cone is characterized by perforations.

FIG. 4 is a cross-sectional view of a preferred embodiment according to the present invention showing a stent pusher that is loaded with a stent which is covered by a catheter having a tapered distal end with a guide wire passing through the stent pusher and the catheter.

FIG. 5 is a cross-sectional view of an alternative embodiment of the present invention showing a stent pusher and a catheter covering the stent along with an inner sleeve which inner sleeve is used to retract the catheter to expose the stent beginning at the stent proximal end and progressing to the stent distal end.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is directed to a stent delivery system. Current stent delivery systems for self-expanding stents typically are constructed as illustrated in FIG. 1. As seen in the cross-sectional view of FIG. 1, a stent delivery system 10 is constructed from tubular-shaped catheter 12 having a distal end 14 and a proximal end 16. Within an inner lumen 18 of the catheter 12 at a distal end 14 is a self-expanding stent 20. The catheter 12 thus keeps the self-expanding stent 20 from expanding until deployment of the stent is desired.

The stent delivery system 10 is tracked over the guide wire 22. Moving along the guide wire 22 is a stent pusher 24 abutting the proximal end 26 of the stent 20. The stent pusher 24 is used to push the stent 20 in order to hold it in place while the catheter 12 is retracted proximally allowing the stent 20 to be exposed to the ambient environment and to expand from the distal end to the proximal end as stent 20 exits catheter 12 via distal end 14. An example of a stent delivery system similar to that described in connection with FIG. 2 is disclosed, for example, in U.S. Patent No. 4,580,568 to Gianturco.

As is illustrated in FIG. 1, because the diameter of the stent 20 with the catheter 12 surrounding it is substantially greater than the diameter of the guide wire 22, there is a large, abrupt increase in diameter transitioning from the guide wire 22 to the catheter 12. The blunt distal end 14 of the catheter 12 can be a significant limitation in negotiating tortuosity in a vessel or in crossing a tight stenosis. It therefore is desirable to make this transition more smooth and less abrupt.

In the conventional design shown in cross-section in FIG. 2, the transition has been modified with a taper. Specifically, in the stent delivery system 30 shown in FIG. 2, the distal end 32 of the catheter 34 is tapered at the region 36. With a tapered distal end 32, the catheter 34 provides a smooth and gradually decreasing transition from the outside diameter of the catheter 32 to the outside diameter of the guide wire 22. The tapered region 36 can be made by heating and stretching the catheter 32 to a smaller diameter. It also is possible to bond a tapered cone onto the distal end 32 of the catheter 34. Such a construction is shown, for example, in U.S. Patent No. 5,458,615 to Klemm et al.

On the other hand, the presence of the tapered region 36 presents problems for deployment of the stent 20. For instance, the distal end 28 of the stent 20 bears a great load when it must push open the tapered region 36 during deployment. This load might distort the profile of the stent 20, cause the stent 20 to hang due to friction with the tapered region 36, damage a stent strut, etc.

In order to minimize the potential for such problems, a stent delivery system 50 according to the present invention employs a unique stent pusher design. FIG. 4 provides a cross-sectional view of a preferred embodiment of the present invention. In this preferred embodiment, the stent delivery system 50 comprises a tubular catheter 52 having an inner lumen 54 extending therethrough leading from a proximal end 56 to a distal end 58. The distal end 58 further preferably includes a tapered region 60.

The catheter 52 partially overlies the stent pusher 62, which has a generally cylindrical shape with a recessed region 64 having a reduced diameter. The recessed region 64 preferably is located proximate to the distal end 66 of the stent pusher 62. The proximal end 68 of the stent pusher 62 extends past the proximal end 56 of the catheter 52 to allow a hand-hold area for the user or cardiologist.

The unexpanded stent 20 is mounted at the recessed region 64 so that the outside diameter of the unexpanded stent 20 is, at most, flush with the outside diameter of the stent pusher 62. The stent pusher 62 further includes a leading

edge 66 adjacent the distal end 28 of the stent 20. The leading edge 66 may be blunt as shown in FIG. 4, or may have a rounded or a cone-shaped profile to control engagement with the tapered region 60. More importantly, with the presence of a leading edge 66, the distal end 28 of the stent 20 thereby is protected.

Moreover, the stent pusher 62 preferably has a leading edge 66 that has a diameter as large as the diameter of the stent 20. Therefore, the profile of the stent 20 likewise is protected.

The leading edge 66 transfers the force encountered to push open the tapered region 60 to the stent pusher 62 instead of bearing the load directly against the distal end 28 of the stent 20, as would occur in the prior art configuration shown in FIG. 2. The stent pusher 62 of the present invention thus provides a force- bearing structure to protect the stent 20.

The stent pusher 62 includes an inner lumen 72 extending coaxially along the length thereof. The guide wire 22 passes through the inner lumen 72, and the stent delivery system 50 tracks over the guide wire 22.

To enhance pushability and maneuverability, the a tapered region 60 optionally may be modified as depicted in FIGS. 3A-3D. The tapered region 60 when modified as shown in FIGS. 3A-3D enables free expansion and allows the stent 20 to be pushed easily therethrough. In particular, FIGS. 3A and 3B show side and front elevational views of an alternative embodiment tapered region 38 that has at least one longitudinal slit 40. As the stent 20 moves into the tapered region 38 stretching the fabric in that area, the slit 40 separates thereby relieving the stress build up. The separating slit also allows the stent 20 to pass more easily through the tapered region 38 because the slit contributes to less resistance.

In another alternative embodiment, shown in the front elevational view of FIG. 3C, the tapered region 42 includes a rolled-up and overlapping area to create a spiral 44. Again, the goal is to permit material in the tapered region 42 to easily separate to permit passage of the stent 20 therethrough. An example of a catheter with such a spiral-fold tip is disclosed in U.S. Patent No. 5,447,503 to Miller.

FIG. 3D shows a side elevational view of the tapered region 46 of another alternative embodiment catheter having perforations 48. As with the construction shown in FIGS. 3A, 3B, and 3C, the perforations 48 allow the diameter of the tapered region 46 to increase as the stent 20 is pushed therethrough. The perforations 48 thus permit a greater degree of stretching in the material forming the tapered region 46 without tearing and with minimal resistance.

FIG. 5 provides a cross-sectional view of an alternative embodiment of a stent delivery system according to the invention. The stent delivery system 74 preferably comprises a catheter 76 having a tapered region 78 at a distal end 80. Partially underlying the catheter 76 is a stent pusher 82, preferably formed in a cylindrical shape, with a distal end 84 and a proximal end 86. Adjacent the distal end 84 is a recessed region 88 to which is mounted an unexpanded stent 20. The stent pusher 82 further includes a leading edge 90 and an inner lumen 92 extending along the length of the stent pusher 82.

Passing through the inner lumen 92 is an inner sleeve 94 having a proximal end 96 and a distal end 98. Preferably, the distal end 80 of the catheter 76 engages the distal end 98 of the inner sleeve 94. The interface may be bonded, mechanically linked, welded, or otherwise attached through processes known in the art. Thus, movement of the catheter 76 is directly linked to movement of the inner sleeve 94. The inner sleeve 94 preferably is rigid to enhance pushability. The inner sleeve 94 further has an inner lumen 100 through which the guide wire 22 passes. The stent delivery system 74 tracks over the guide wire 22.

In order to minimize the load encountered by the distal end 28 of the stent 20, the stent delivery system 74 of FIG. 5 provides a leading edge 90, which is connected to or which is unitary or one piece with the stent pusher 82, as a load-bearing structure. It is noted that the edge 90 is load-bearing as a puller, but does not protect the edge of the stent as in FIG. 4 because the stent is moving in the opposite direction. Further, the outside diameter of the stent 20 as the stent is mounted to the recessed region 88 preferably is equivalent to the outside diameter of

the leading edge 90 and the stent pusher 82. This is preferable because the stent 20 is pushing out against the catheter 76, and it sometimes is impractical to keep the outside diameter of the leading edge 90 always larger than the outside diameter of the stent 20. It can be sufficient if the outside diameter of the leading edge 90 and the outside diameter of the stent 20 are equivalent diameters within manufacturing tolerances.

In an alternative embodiment, the outside diameter of the stent 20 as it is mounted to the recessed region 88 is, at most, equal to the outside diameter of the leading edge 90 and the stent pusher 82.

The alternate embodiment stent delivery system 74 shown in FIG. 5 operates to allow the stent 20 to expand beginning at the proximal end of the stent and progressing to the distal end of the stent until the stent is fully expanded. In operation, the catheter 76 is advanced distally of the stent 20 by the cardiologist when the cardiologist pushes the inner sleeve 94 in a distal direction while holding the stent pusher 82 immobile. Conceptually speaking, the stent pusher 82 actually is a "stent puller" in this configuration. In the exemplary embodiment shown in FIG. 5, the stent delivery system 74 enjoys a smooth transition at the distal tapered region 78 to allow the stent delivery system 74 to negotiate the tortuous anatomy of the patient freely and to cross lesions therein smoothly. The distal tapered region 78 also can be very accurately placed on the proximal end 29 of the stent 20. This especially is useful in ostial lesions or when it is desired to deploy a stent near a bifurcation.

The alternative embodiment of the stent delivery system 74 shown in FIG. 5 does have a larger profile than other of the embodiments, because of the space which is occupied by the inner sleeve 94. This of course assumes that stent 20 itself does not require a larger profile to fit all of its struts. In using the stent delivery system 74 of FIG. 5, the cardiologist must check to insure that there is sufficient space in the vessel distally of the lesion in which the catheter 76 can be advanced while deploying the stent 20. Lastly, the stent delivery system 74 of FIG. 5 may

provide less protection than do other embodiments against introducing into the patient's circulation emboli, which may be loosened from the arterial wall during deployment of the stent.

In each of the exemplary embodiments, the stent delivery system components may be made from a variety of materials known in the art. Such materials include polyamide, polyetheretherketone (PEEK), polyethylene terephthalate (PET), polytetrafluorethylene (PTFE), polyolefin, silicone, polyurethane, nylon, or the like. The bond used between the interface of the distal end 80 of the catheter 76 and the distal end 98 of the inner sleeve 94 can be any adhesive known in the art, including acrylonitrile-based adhesives. The catheter, inner sleeve, tapered region, and like components should be formed from material that is of sufficient strength and/or wall thickness so that the materials will retain the cylindrical shape when the stent delivery system is introduced into and removed from the patient.

The stent used with a stent delivery system according to the present invention can have any configuration or pattern known in the art and preferably is formed from self-expanding metals including stainless steel or nickel-titanium (both shape memory and stress-induced martensite nickel-titanium), or from other shape memory or pseudoelastic alloys.

While the present invention has been described herein in terms of certain preferred embodiments, those skilled in the art will recognize that various modifications can be made. To be sure, while the present invention has been described herein in terms of delivering an expandable stent to a target site within a patient's body lumen, the delivery system also can be employed to deliver stents to locations within other body lumens such as the urethra or the Fallopian tubes, so that the stents can be expanded to maintain the patency of these body lumens. Various changes and improvements also may be made to the present invention without departing from the scope thereof.

The preceding description and illustrative drawing figures apply to stent delivery systems for delivering stents of the self-expanding type. However, the

inner sleeve and proximal to distal movement of the sheath of the stent delivery system according to the present invention could be used with balloon expandable stents as well, and such an application thus is contemplated. In the case of stents of the balloon-expandable type, the stent pusher is not necessary.

WHAT IS CLAIMED IS:

1. A stent delivery system for delivering a stent to a patient's body lumen, comprising:

a catheter having a tapered and pliable distal end, a proximal end, and an inner lumen;

a stent pusher having a leading edge at a distal end, a recessed region proximate to the distal end, and a proximal end, wherein the stent pusher is disposed at least partially within the inner lumen of the catheter, and wherein the stent pusher includes an inner lumen; and

a stent disposed on the recessed region of the stent pusher.

2. The stent delivery system of claim 1, wherein a guide wire extends through the inner lumen of the stent pusher.

3. The stent delivery system of claim 1, wherein the leading edge of the stent pusher includes a diameter that is slightly smaller than the diameter of the inner lumen of the catheter.

4. The stent delivery system of claim 1, wherein the tapered distal end of the catheter includes a longitudinal slit.

5. The stent delivery system of claim 1, wherein the tapered distal end of the catheter includes perforations.

6. The stent delivery system of claim 1, wherein the tapered distal end of the catheter includes overlapping surfaces forming a spiral.

7. The stent delivery system of claim 1, further comprising an inner sleeve which is disposed coaxially over the guide wire and which has a distal end that is attached to the tapered and pliable distal end of the catheter, and wherein the stent pusher is disposed coaxially over the inner sleeve.

8. The stent delivery system of claim 7, wherein the distal end of the inner sleeve is tapered.

9. The stent delivery system of claim 7, wherein the distal end of the inner sleeve extends beyond the tapered and pliable distal end of the catheter.

10. The stent delivery system of claim 1, wherein one or more of the components are formed from at least one material selected from the group consisting of polyamide, polyetheretherketone (PEEK), polyethylene terephthalate (PET), polytetrafluorethylene (PTFE), polyolefin, silicone, nylon, or polyurethane.

11. A stent delivery system for delivering a stent to a patient's body lumen, comprising:

a tubular catheter having a tapered and pliable distal end, a proximal end, and an inner lumen extending therethrough;

a cylindrically-shaped stent pusher having a substantially rigid proximal end, a leading edge at a distal end defining a first diameter, a recessed region of the stent pusher to receive the stent and having a second diameter that is smaller than the first diameter, so that an outside diameter of the stent when the stent is disposed about the recessed region is at most equal to the first diameter, and an inner lumen of the stent pusher extending coaxially therethrough;

wherein the stent pusher is disposed at least partially within the catheter lumen.

12. The stent delivery system of claim 11, wherein a guide wire extends through the inner lumen of the stent pusher.

13. The stent delivery system of claim 12, further comprising an inner sleeve which extends coaxially over the guide wire and through the inner lumen of the stent pusher, the inner sleeve having a length that is longer than the length of the stent pusher and which includes a distal end that is attached to the tapered and pliable distal end of the catheter.

14. The stent delivery system of claim 13, wherein the inner sleeve is at least partially formed of a rigid material.

15. The stent delivery system of claim 13, wherein the distal end of the inner sleeve includes a taper.

16. The stent delivery system of claim 13, wherein the distal end of the inner sleeve is bonded to the distal end of the catheter.

17. The stent delivery system of claim 11, wherein the outside diameter of the stent is approximately equivalent to the second diameter of the stent pusher.

18. A method for delivering a stent to a patient's body lumen, comprising the steps of:

providing a tubular catheter having a tapered and pliable distal end, a proximal end, and an inner lumen extending therethrough;

providing a rigid, cylindrically-shaped stent pusher having a proximal end, and a leading edge at a distal end defining a first diameter;

providing a recessed region of the stent pusher to receive the stent having a second diameter that is smaller than the first diameter so that an outside diameter of the stent is at most equivalent to the first diameter defined by the leading edge of the distal end of the stent pusher;

providing an inner lumen that extends through the stent pusher;

disposing the stent pusher at least partially within the catheter inner lumen;

providing a guide wire extending through the inner lumen of the stent pusher; and

translating the catheter relative to the stent pusher to expose the stent via the distal end of the catheter.

19. The method of claim 18, wherein the step of translating the stent further comprises holding the stent pusher in a stationary position while translating the catheter in a proximal direction.

20. The method of claim 18, wherein the method further comprises providing a longitudinal slit in the tapered and pliable distal end of the catheter.

21. The method of claim 18, wherein the method further comprises providing perforations in the tapered and pliable distal end of the catheter.

22. The method of claim 18, wherein the method further comprises providing overlapping surfaces forming a spiral in the tapered pliable distal end of the catheter.

23. The method of claim 18, wherein the method further comprises providing a rigid inner sleeve that extends coaxially over the wire and through the inner lumen of the stent pusher, the inner sleeve having a length that is longer than the length of the stent pusher and which includes a distal end that is attached to the tapered and pliable distal end of the catheter.

24. The method of claim 23, wherein the method further comprises translating the inner sleeve in a distal direction, while holding the stent pusher immobile.

25. The method of claim 23, wherein the method further comprises translating the catheter relative to the stent pusher to expose a proximal end of the stent before exposing a distal end of the stent.

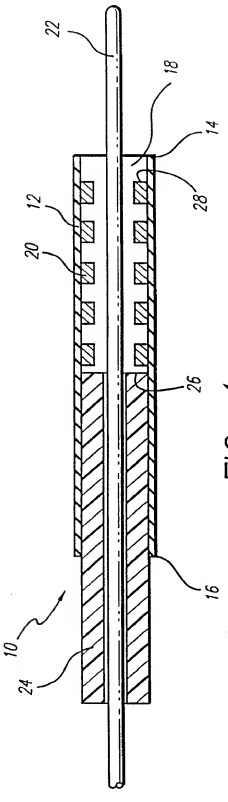

FIG. 1
PRIOR ART

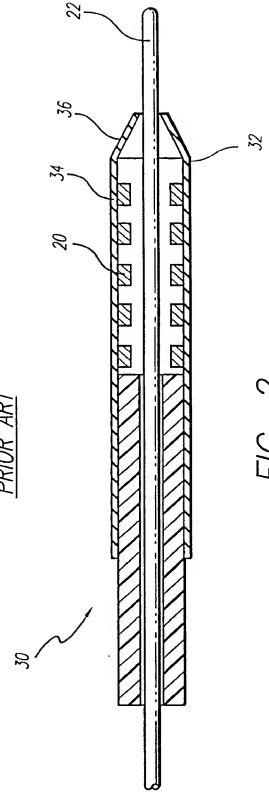

FIG. 2
PRIOR ART

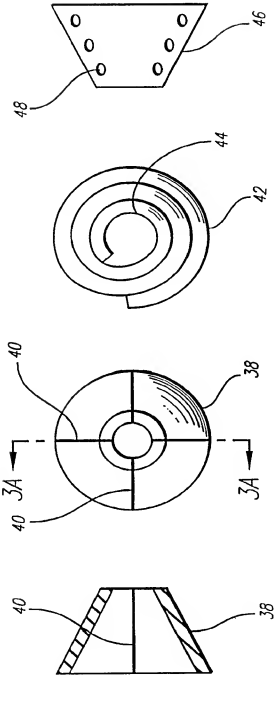

FIG. 3A FIG. 3B FIG. 3C FIG. 3D

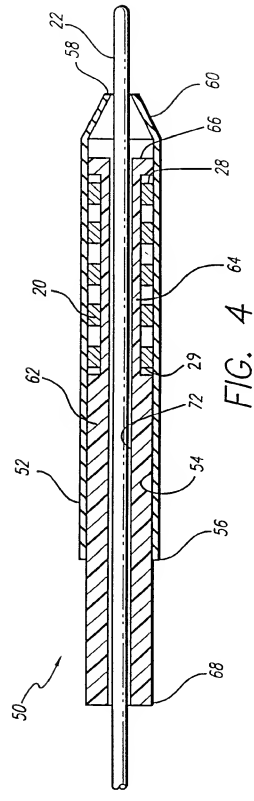
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FIG. 4

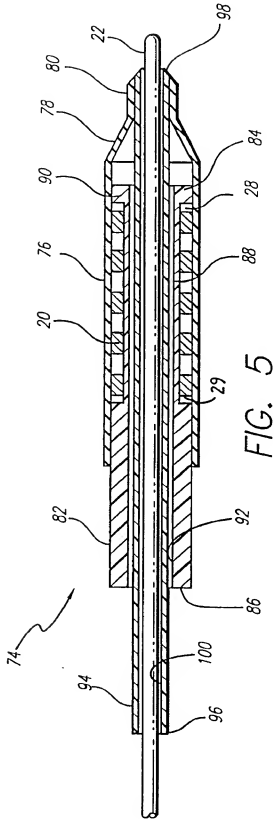
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FIG. 5

INTERNATIONAL SEARCH REPORT

Inter onal Application No
PCT/US 00/13668

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, INSPEC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 735 859 A (FISCHELL ROBERT E ET AL) 7 April 1998 (1998-04-07)	1-5,10
A	column 2, line 65 -column 3, line 52; figures 1-5 column 4, line 3 - line 67; figure 7	7-9, 11-17
A	US 5 201 757 A (HEYN LAWRENCE R ET AL) 13 April 1993 (1993-04-13) column 5, line 10 -column 8, line 10; figures 2,4-5D	1-3,7, 9-13,16, 17
A	US 5 447 503 A (MILLER JAY F) 5 September 1995 (1995-09-05) cited in the application column 2, line 45 -column 3, line 54; figures 2-6	1-4,6, 11,12

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[X] Further documents are listed in the continuation of box C. [X] Patent family members are listed in annex.

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"A" document defining the general state of the art which is not considered to be of particular relevance

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 August 2000	05/09/2000

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

Inter onal Application No
PCT/US 00/13668

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
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A	US 4 665 918 A (GARZA GILBERT A ET AL) 19 May 1987 (1987-05-19) column 3, line 1 - line 24; figure 1 column 3, line 48 - line 64; figures 5,6 column 4, line 46 -column 5, line 56; figures 9A,10A,11A,12A,13A	1-3,11, 12,17

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INTERNATIONAL SEARCH REPORT

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